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Dockets Management Branch
(HFA-305)
Food & Drug Administration
Room 4-62
5600 Fishers Lane
Rockville, Maryland 20857

RE: Skin Bleaching Drug Products for Over the Counter Human Use; Tentative Final Monograph Docket No. 78N-0065.

OBJECTIONS TO AND COMMENTS ON PROPOSED FDA, OTC LABELLING. RECOMMENDATIONS FOR HYDROQUINONE.

Dear Sir or Madam:

Keystone Laboratories is a manufacturer of skin care products, among them, the Ultra Glow Brand of Skin Tone Creams which contain Hydroquinone as an active ingredient.

Following publication in the Federal Register of September 3rd (Vol. 47, No. 172), Docket number 78N-0065, concerning product labelling or products containing Hydroquinone, we have the following comments:

1) The use of the word Skin Bleach or Skin Lightener suggests that these products permanently or completely depigment the skin. This is not a clear or truthful description.

2) The word "Bleach" and "Lightener" is offensive to black consumers and the true benefits of using these products may not be realized because of the implication of bleach or a caustic material.

   Some years ago the above mentioned brand was named "Bleach 'n Glow" but in response to consumer preference its name was changed.

3) On page 39111 of the Federal Register (bottom of first column) it states "The agency believes that consumers are familiar with the term "skin bleaching" and that the use of this term along with the indications for the product contained 358.50 (b) (Indications Statement) accurately describe for consumers the pharmacologic results to be obtained from using these products."

   The agency has no foundation in the record for its "belief" and we believe that the use of a number of other terms, such as Skin Tone Cream or Fade Cream are more appropriate. The words in Skin Tone Cream and Fade Cream are more acceptable and accurately describe the product as these are the words used in current common parlance by users of these products.

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The agency's "belief" that the continued use of the words "Skin Tone Cream" therefore are unfounded.

4) FDA objections to the use of the word "even" color....." in fact, Hydroquinone would exert its action on all pigment" (Pg. 3111, Col. 3). Any change from current terminology is objected to as the FDA has no support in the literature quoted to support in this hypothesis. (Arndt and Fitzpatrick). In fact it is stated in the same paper that the "effectiveness" of Hydroquinone appeared to depend on the type of Hypermelanosis.

   Tentative directions further state that the product should be applied only to hyperpigmented areas and not over wide areas, this would result in an uneven, blotchy skin.

5) Use of product by children under twelve.

   A simple caution is all that is required. "Do not use on children under 12 years of age." These products are not marketed to children so it is unlikely they would use the product anyway.

6) Use/Non use of Sunscreens

   The current proposed wording is lengthy. We recommend that advisory copy on packages such as "excessive exposure to sun should be avoided"

7) Many packages contain only a small surface area on which to print claims and other pertinent information. If the proposed monograph is adhered to in its entirety, it is likely that very few "cosmetic" claims could appear.

The criteria which should guide the agency in its final monograph is that these products are essentially used for cosmetic purposes by the public. The over-abundance of "Drug" wording may confuse and deter product use.

Andrew C. Inglis
Marketing Director